

April 2, 2019



# **Adaptimmune Presents Safety Data with Evidence of Tumor Necrosis in One Patient from ADP-A2AFP Study at American Association for Cancer Research (AACR) Meeting**

PHILADELPHIA and OXFORD, United Kingdom, April 02, 2019 (GLOBE NEWSWIRE) -- Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in T-cell therapy to treat cancer, presented initial safety data from two patients with advanced hepatocellular carcinoma (HCC), liver cancer, from the first dose cohort of the ADP-A2AFP study at the annual AACR meeting.

"We did not observe clinically significant liver toxicity in the two patients treated at a dose of 100 million transduced cells, and these data supported dose escalation to the second cohort. Even though data are preliminary, we are encouraged by the evidence of tumor necrosis we saw in one of the two patients. We have started dosing patients with higher cell doses and there continues to be no evidence of hepatotoxicity or other dose limiting toxicities. We will give an update on this study as well as our other ongoing trials during our May quarterly call," said Rafael Amado, Adaptimmune's President of Research & Development.

There was no evidence of clinically significant hepatotoxicity, off-target toxicity, or alloreactivity, and no protocol-defined dose limiting toxicities were observed. Most adverse events were consistent with those typically experienced by cancer patients undergoing cytotoxic chemotherapy or other cancer immunotherapies.

Imaging and a post-treatment biopsy for one patient showed evidence of tumor necrosis with lymphocytic infiltration, concurrent with a transient decrease in serum AFP. In addition, ADP-A2AFP SPEAR T-cells were detectable in the peripheral blood. The patient later progressed at Week 16.

Based on these initial safety data, the Safety Review Committee (SRC) endorsed advancing to Cohort 2 (<https://bit.ly/2M0oQxe>).

## **Overview of study design:**

- This is a first-in-human study to evaluate safety and antitumor activity of SPEAR T-cells (ADP-A2AFP) directed towards AFP in patients with HCC not amenable to transplant, resection, or loco-regional therapy and failed/intolerant/refused standard of care treatment (NCT03132792)
- Up to 20 patients will be enrolled using a modified 3+3 design, in three dose escalation cohorts followed by an expansion phase:

- Cohort 1: target dose of 100 million transduced cells (range: 80-120 million); lymphodepletion regimen of cyclophosphamide (Cy) (500 mg/m<sup>2</sup>) and fludarabine (Flu) (20 mg/m<sup>2</sup>) x 3 days: stagger of 21 days between patients to evaluate dose limiting toxicities (DLTs)
- Cohort 2: target dose of 1 billion transduced cells (range: 500 million to 1.2 billion); lymphodepletion regimen of Cy (500 mg/m<sup>2</sup>) and Flu (20 mg/m<sup>2</sup>) x 3 days: stagger of 7 days between patients to evaluate DLTs
- Cohort 3: target dose of 5 billion transduced cells (range: 1.2 to 6 billion); lymphodepletion regimen of Cy (600 mg/m<sup>2</sup>) x 3 days and Flu (30 mg/m<sup>2</sup>) x 4 days; stagger of 7 days between patients to evaluate DLTs
- Expansion Phase: target dose of 5 billion transduced cells (range: 1.2 to 10 billion); lymphodepletion regimen of Cy (600 mg/m<sup>2</sup>) x 3 days and Flu (30 mg/m<sup>2</sup>) x 4 days; no stagger between patients

#### **Poster presentation details:**

- **Title:** Initial safety of AFP SPEAR T-cells in patients with advanced hepatocellular carcinoma
- **Session Title:** Adoptive Cell Therapy 3
- **Session Date and Time:** Tuesday Apr 2, 2019 8:00 AM - 12:00 PM ET
- **Location:** Georgia World Congress Center, Exhibit Hall B, Poster Section 22
- **Poster Board Number:** 6
- **Abstract Number:** 3183

#### **About Adaptimmune**

Adaptimmune is a clinical-stage biopharmaceutical company focused on the development of novel cancer immunotherapy products. The Company's unique SPEAR (Specific Peptide Enhanced Affinity Receptor) T-cell platform enables the engineering of T-cells to target and destroy cancer, including solid tumors. Adaptimmune is currently conducting clinical trials with SPEAR T-cells targeting MAGE-A4, MAGE-A10, and AFP across multiple solid tumor indications. The Company is located in Philadelphia, USA and Oxfordshire and Stevenage, UK. For more information, please visit <http://www.adaptimmune.com>.

#### **Forward-Looking Statements**

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). These forward-looking statements involve certain risks and uncertainties. Such risks and uncertainties could cause our actual results to differ materially from those indicated by such forward-looking statements, and include, without limitation: the success, cost and timing of our product development activities and clinical trials and our ability to successfully advance our TCR therapeutic candidates through the regulatory and commercialization processes. For a further description of the risks and uncertainties that could cause our actual results to differ materially from those expressed in these forward-looking statements, as well as risks relating to our business in general, we refer you to our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 27, 2019, and our other SEC filings. The forward-looking statements contained in this press release speak only as of the date the statements were made and we do not undertake any obligation to update such forward-looking statements to reflect subsequent events or circumstances.

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